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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,538	03/20/2001	Mary A. Reppy	2001/00005	9053

7590

09/06/2002

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 09/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,538

Applicant(s)

REPPY ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 20-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 9,10,15,16,18 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Applicant's amendment filed on 6/24/02 in Paper No. 6 is acknowledged and entered. Claims 1 and 11 are amended. Claims 20-46 have been withdrawn from further consideration a being drawn to a non-elected invention. Claims 1-46 are pending.

Claim Objections

2. The previous objection made of record for Claims 9-10, 15-16, and 18-19 are maintained. However, applicant has indicated that replacement pages 38, 39, and 40 were submitted to overcome this objection. These pages were not included with the amendment filed on 6/24/02 in Paper No. 6, therefore the objection is maintained.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "leads to a change in fluorescence" of Claim 1 is vague and indefinite because it does not recites a positive recitation. Is the change in fluorescence due to the analyte binding or reaction with the substrate? The claim language should indicate that the actual binding or reacting of the analyte with the substrate causes a change in fluorescence of the polydiacetylene backbone.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saul et al. (US Patent 5,415,999) in view of Charych et al. (US Patent 6,180,135 B1) for reason of record.

Response to Arguments

7. Applicant's arguments filed 6/24/02 have been fully considered but they are not persuasive.

8. Applicant argues that Saul et al. fails to suggest the present invention since Saul et al. is not concerned with a change in fluorescence of a polydiacetylene backbone. The examiner deems that this is not the case for in Claim 1 of Saul et al. the "fluorescer" is comprised of a macromolecular analyte-specific ligand which is associated with the polymerized polydiacetylene lipid layer (col. 14, lines 36-39). This "fluorescer" is the same as the polydiacetylene backbone and substrate that has direct affinity for the analyte of the instant claimed invention. The method of Saul et al. in Claim 1 for detecting the presence of an analyte in a sample is comprised of detecting the modulation of fluorescence of the "fluorescer" upon binding to the analyte. This method of Saul et al., which measures the change in fluorescence

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that is due to the interaction or binding of an analyte to the “fluorescer” that contains the polydiacetylene, is the same as the method of the instant Claim 1.

Further, the “comprises” terminology of the instant Claim 1 is open-ended and does not exclude possible additional elements such as those described by Saul et al.

9. In response to applicant's argument that there is no suggestion to combine the references (Saul et al. (US Patent 5,415,999) and Charych et al. (US Patent 6,180,135 B1)), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, there is a motivation for substituting the polydiacetylene of Charych et al. in the method of Saul et al. Both Saul et al. and Charych et al. discloses the same type of polydiacetylene, which is 10, 12-pentacosadiynoic acid (Saul: col. 5, lines 1-16; Charych: col. 19, lines 4-10). Charych et al. teaches that the polydiacetylene can be used in the colorimetric method of detection and Saul et al. teaches that the polydiacetylene can be used in the fluorescence method of detection. This would suggest that polydiacetylene would be useful in either the method of colorimetric detection or the method of fluorescence detection. Therefore, one would have had reasonable expectation of success of substituting the polydiacetylene of Charych et al. in the method of Saul et al. because both Saul et al. and Charych et al. disclose that the same type of polydiacetylene would be useful in two different methods of detection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

mct

September 5, 2002



MARY E. CEPERLEY
PRIMARY EXAMINER

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